REMARKS

Claim 4 has been amended to provide proper Markush language and should now overcome the rejection raised under 35 U.S.C. 112, second paragraph. Claims 1-5 and 12-16 are pending in the application.

All claims stand rejected under 35 USC § 103(a) as obvious over Muehlradt (US 6,573,242). In addition, claims 1, 2, 4, 5, and 15 stand rejected for obviousness type double patenting over claims 8 and 9 of U.S. Patent 6,573,242 to Muehlradt. Both rejections are traversed without further amendment.

As is recognized by the Examiner the Muehlradt reference has an inventor in common with the present application. In addition, the two cases are owned by the same entity.

A text search of the Muehlradt reference reveals that at no point does Muehlradt discuss mucosal delivery. Further, Muehlradt does not at any point discuss or suggest using a lipopeptide or lipoprotein of the structure set forth in claim 1 (e.g., MALP-2) as an adjuvant provided to the mucous membranes of an animal or human to stimulate an immunogenic response for an antigen which will also be provided to the mucous membranes of the animal or human.

The Examiner has reasoned that the statement that the dihydroxypropyl cysteine peptides described in Muehlradt could be used as a "vaccine adjuvant (admixture with a vaccine)" (column 2, lines 6-7) would it make it obvious to one of ordinary skill in the art that at least some of those dihydroxyproply cysteine peptides (e.g., those specified in claim 1 of the present application), and MALP-2 in particular, would be functional as a mucosal adjuvant and that it would be obvious for a person to try these compounds, from amongst all possibilities, as mucosal adjuvants. This reasoning does not comport with current case law, overlooks evidence in the patent application itself which demonstrates that the discovery that MALP-2 would be functional as a mucosal adjuvant, overlooks the requirement in claim 1 that both the antigen and the lipopeptide or lipoprotein are provided to the mucous membranes, and minimizes the declaration of the inventor, Dr. Muehlradt, who is well versed in this technology, is the inventor on the Muehlradt reference, and included supporting documentation for the evidence provided in the declaration.

In re Kubin 561 F.3d 1351 (Fed. Cir. 2009) specifically dealt with when an "obvious to try" rejection is proper. The Court found that there are two situations in which "obvious-to-try" is an appropriate argument under 35 U.S.C. 103. First, when a skilled artisan merely pursues "known options" for a "finite number of identified, predictable solutions". Second, where the improvement is no more than the predictable use of prior art elements according to their established functions. The Court in *In re Kubin* indicated that "obvious to try" is an improper basis of rejection where what would have been allegedly obvious to try was to vary all the parameters or to try each of numerous possible choices until arriving at a successful result where the prior art gave either no indication of critical parameters or any other direction as to which of many possible choices are likely to be successful.

In the present case, the patent application itself establishes that the using compounds like MALP-2 as a mucosal adjuvant was surprising. With reference to Example 1 on pages 20 and 21 of the application, it can be seen that *in vitro* experimentation with MALP-2 indicated that it had little or no potential as a mucosal adjuvant. Similarly, Example 2 on pages 21-23 of the application, and with reference to Figure 4, it was found that increasing doses of MALP-2 led to an abolition of the adjuvant effect, and this would have made it not possible to discern the mucosal adjuvant effect at standard concentrations used for other lipopeptides. Further, in Example 3, at the bottom of page 24 of the application it is noted that the results in Figure 5 demonstrate that the use of MALP-2 in higher dosages not only leads to humoral responses no longer being detectable, but also the cell mediated immunogenicity being reduced. However, the inventor, by continued experimentation was able clearly demonstrate that MALP-2 could be used as a potent mucosal adjuvant (see Examples 5 and 9, etc.). Further, the inventor demonstrated that the intranasal route (administration to mucous membranes) was far more effective than when administered by intraperitoneal administration. The result is quite significant as there are currently no effective adjuvants that are approved for intranasal immunization of human patients.

As noted previously, a complete reading of the Muehlradt reference reveals that it provides no information whatsoever which would lead one of ordinary skill in the art to try MALP-2 as a mucosal adjuvant. Not only does the Muehlradt reference provide no guidance on the parameters of administration, the selection of MALP-2 as a mucosal adjuvant candidate amongst other lipopeptides and other mucosal adjuvants, or the indication that MALP-2, among other possible choices would be successful. In fact, some of the types of experiments detailed in

the present application could have easily lead one of ordinary skill in the art away from the use of MALP-2 as a mucosal adjuvant.

Furthermore, as established by the Rule 132 declaration of Muehlradt, the ability to use MALP-2 as a mucosal adjuvant was not even publicly revealed until 2002 (see Declaration at section 5), which is well after the 1998 publication date of International Application PCT/EP97/07090 (from which the Muehlradt reference claims priority). In addition, as established by the Rule 132 declaration of Muehlradt, a macrophage stimulator such as MALP-2 is not *a priori* an adjuvant, would be understood by those of skill in the art to not necessarily by a mucosal adjuvant (see Declaration at section 4). As pointed out in the Rule 132 declaration of Muehlradt, the effectiveness of a known adjuvant in a new experimental setting cannot be foreseen (see Declaration at section 6). Thus, any reasoning that mucosal adjuvants are known by one of ordinary skill in the art, and that this would make it obvious to try MALP-2 as a mucosal adjuvant is simply faulty and does not comport with what is known about one of ordinary skill in the art (see Declaration at sections 2 and 6).

Thus, until the experimental work was conducted, as is detailed only in Examples 1-9 of the application (no experiments or indications of success as a mucosal adjuvant being indicated in Muehlradt), one of ordinary skill in the art could not have foreseen the extraordinary properties and benefits of the claimed lipopeptides (MALP-2 in particular) from Muehlradt. Further, one of ordinary skill in the art would have absolutely no way of knowing or even guessing with any degree of accuracy (which is much less than the standard required in *In re Kubin*) that having both an antigen and MALP-2 delivered to a patient through mucous membranes would provide for an effective vaccine (as is required in the claimed invention).

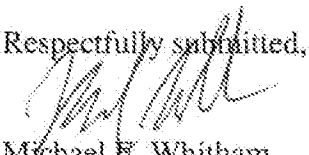
Further, it is noted that claims of similar scope to the present application stemming from the same International Application have issued in other parts of the world. See particularly, European Patent EP1490106, or Australian Patent AU 2003226777.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: mike@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If an extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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